

REMARKS

Claims 1 and 3-54 are pending in the current application. Claim 2 was previously cancelled without prejudice or disclaimer of the cancelled subject matter. Claims 53 and 54 are newly added. Applicants reserve the right to pursue the subject matter of the cancelled claims in one or more continuing or divisional applications. Claims 1, 7, 8, 10, 13, 23 and 34 are newly amended herein.

Support for the amendments ("hydrophobic solvent or solvents have a solubility in water of less than 1 wt%") to claims 1, 7, 10, 13 and 34 is found, for example, on page 6, lines 8-11; page 8, lines 14-21 (providing support for more than one hydrophobic solvent); and elsewhere throughout the specification.

Support for the amendments to claim 7 ("no greater") is found, for example, on page 5, line 11; page 14, line 8 "through a 20 gauge needle," and elsewhere throughout the specification.

Support for the amendment to claims 8, 13, 23, and 34 ("or equal to") is found, for example, on page 14, line 18; and elsewhere throughout the specification.

Support for newly added claims 53 and 54 is found, for example, in claims 23 and 24 as originally filed. Original claims 23 and 24 were explicitly declared allowable by the Examiner in the Office Action dated March 25, 2004. Original claims 23 and 24 were again declared allowable in the Office Action dated July 26, 2005 because they were not identified as being rejected. Applicants included original claims 23 and 24 herein in order to move them towards (original claims 23 and 24, now claims 53 and 54) allowance and issue.

The amendments are not believed to introduce new matter and entry is respectfully requested.

A. PERSONAL INTERVIEW

Applicants thank the Examiner for the personal interview held with the undersigned on October 19, 2006. During the interview, the rejection under 35 U.S.C. § 112, first paragraph, and the rejection under 35 U.S.C. § 102(b) were discussed. Methods for overcoming each rejection were discussed. The Examiner suggested the specific

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species not disclosed by the reference might be claimed. In addition, original claims 23 and 24 were discussed.

B. IDS AND PTO 1449 FORMS

A review of the file indicates that page 4 of the PTO 1449 form, date stamped May 23, 2002 has not been returned by the Office with a subsequent communication. The Office is respectfully requested to return a copy of executed page 4 of said PTO 1449 form to Applicants with any subsequent correspondence.

C. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 7 (and 8), 13-20, 23, 24, 29-40 and 41-50 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The rejection is respectfully traversed. Claims 7, 8, 13, 23 and 34 are newly amended herein. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

At Office Action page 2, the Examiner asserts the phrase “having a diameter smaller than that of a 20 gauge needle” allegedly lacks support in the specification. Without acquiescing to the merits of the rejection, claim 7 has been amended to recite “no greater than that of a 20 gauge needle” as recommended by the Examiner. Support for the amendment to the claim is found, for example, at page 5, line 11, and elsewhere throughout the specification.

At page 3 of the Office Action, the Examiner rejects claims 8, 13, 23 and 34, alleging the phrase “less than 2000 centipoise” lacks support in the specification. Contrary to the position of the Examiner, support for the exact phrase is found, for example, in original filed claim 8, and elsewhere throughout the specification. Applicant is not required to limit claims 8, 13, 23 and 34, to the phraseology pointed out by the Examiner in view of the literal support for the current claim language in the as-filed specification.

The amendments to the claims are believed to overcome the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

D. CLAIM REJECTIONS 35 U.S.C. § 102(b)

Claims 1-25, 29 and 33-52 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Merck & Co., Inc. WO 99/47073 ['073]. The rejection is respectfully traversed. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order. Claim 2 is newly cancelled. Claims 1, 7, 8, 10, 13, 23 and 34, are newly amended herein.

The Office arguments at pages 3-5 are summarized as follows: Allegedly, the WO'073 document discloses a liquid polymeric composition for controlled release of a bioactive. The liquid polymeric composition comprises a solvent mixture of a hydrophobic solvent and a hydrophilic solvent, a bioerodible polymer and a drug. In particular, the Examiner alleges "[t]he solubility of the hydrophobic solvent is inherent to the solvents used and is also disclosed as less than 1% at page 26, line 26." Office Action at 4.

As the Office is aware, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). However, in the instant case, and contrary to the position of the Office, WO'073 does not anticipate claims 1-25, 29 and 33-52. The Office, in alleging "[t]he solubility of the hydrophobic solvent is inherent to the solvents used and is also disclosed as less than 1% at page 26, line 26" (Office Action at 4) has incorrectly characterized the teachings of the reference.

The WO'073 document, at page 26, line 26, recites that the "as less than 1%" refers to a "hydrophobic bioactive substance" and not a "hydrophobic solvent" as the Office alleges. A "hydrophobic bioactive substance" is defined in the WO'073 document at page 26, lines 24-32, as a "compound useful in human or animal health having a water solubility of <2%, preferably <1%, at room temperature." Examples of hydrophobic bioactive substances are, for example, avermectins, milbemycins and estradiol. Although the listed compounds may be hydrophobic, none are solvents as currently claimed in claim 1. In fact, page 17, lines 12-14, describes avermectins and milbemycins as potent anthelmintic and antiparasitic compounds. Estradiol is a steroid. Page 8, line 30, through

page 9, line 3, provides further insight into the definition of “**bioactive substance**” as intended in the WO’073 application.

At WO’073 page 27, line 10, the ‘073 document describes the phrase “**lipophilic solvents**” means water immiscible solvents, preferably with a solubility in water of less than 10% at room temperature. Thus, although WO’073 describes use of lipophilic solvents (or hydrophobic solvents) (e.g., lipophilic solvents, WO’073 page 7, lines 15-16; page 10, line 33 through page 11, line 14), the WO’073 document does not point out with specificity the use of hydrophobic solvents having a solubility of “less than 1 wt% in water” as is currently claimed.

The Office notes the solubility of a solvent is an inherent property of the solvent, and therefore, inherently taught by the WO’073 document. However, in order to anticipate the claims, the claimed subject matter must be disclosed in the reference with “sufficient specificity to constitute an anticipation under the statute.” What constitutes a “sufficient specificity” is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, it may be reasonable to conclude that the narrow range is not disclosed with “sufficient specificity” to constitute an anticipation of the claims. *See*, MPEP § 2131.03 II. The question of “sufficient specificity” is similar to that of “clearly envisaging” a species from a generic teaching. In the instant case, a claimed composition comprising *inter alia*, a hydrophobic solvent or solvents having less than 1 wt% solubility in water is not envisioned “sufficient specificity” from the genus of “lipophilic solvents” having solubility in water of less than 10% at room temperature. The WO’073 document, failing to specifically point out any advantage to any specific range of solubilities, let alone solvents having a solubility of “less than 1 wt% in water,” fails to anticipate claims 1-25, 29 and 33-52.

For at least these reasons, the WO’073 document does not anticipate the invention claimed in claims 1-25, 29 and 33-52. Reconsideration and withdrawal of the rejection is respectfully requested.

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CONCLUSION

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.

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Date

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